IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Baltimore Division

PAUL NEIL SMITH,
205 East Joppa Road
Towson, MD 21286

and

NORMA SUE GIBSON LANNING,
102 Robert Floyd Dr.
Apt. D
Lexington, NC 27295

and

JIMMY D. BLANTON,
207 Walnut Street
Gaffney, SC 29340

and all others similarly situated,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC.
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26505
with service on
CSC-Lawyers Incorporating Service Co.
7 St. Paul Street, Suite 1660
Baltimore, MD 21202

and

TEVA BIOPHARMACEUTICALS USA, INC.,
9410 Key West Avenue
Rockville, MD 20850
with service on
CSC-Lawyers Incorporating Service Co.
7 St. Paul Street, Suite 1660
Baltimore, MD 21202

Case No.

and

PROPST DISTRIBUTION, INC.,
doing business as and/or formerly known as
Qualitest Pharmaceuticals, Inc.,
130 Vintage Drive
Huntsville, AL 35811
with service on
William S. Propst, Sr.
301 Meridian Street, Suite 101
Huntsville, AL 35801

and

VINTAGE PHARMACEUTICALS, LLC,
doing business as , successor in interest to and/or formerly known as
Qualitest Pharmaceuticals, Inc.,
130 Vintage Drive
Huntsville, AL 35811
with service on
CSC Lawyers Incorporating Service, Inc.
150 South Perry Street
Montgomery, 36104

Defendants.

COMPLAINT
(Products Liability, Punitive Damages, Class Action)

INTRODUCTION

1. This action consists of individual complaints for personal injury and, alternatively a class action. Both sets of claims involve the chemical propoxyphene, marketed both under the brand names Darvocet™ and Darvon™, and generically, as in this case.

2. Propoxyphene was sold in the formulations implicated in this case since the 1970's, when it was approved, until it was recalled on November 19 of 2010.

3. Both the Named Plaintiffs and Class Plaintiffs suffered injuries as a result of taking propoxyphene.

JURISDICTION AND VENUE

4. Jurisdiction and venue is founded upon 28 U.S.C. §1332(a), as no Named Plaintiff is of the same state as any Defendant, as set forth below, and alternately 28 U.S.C. §1332(d), as this Complaint sets forth class action allegations requiring federal jurisdiction under the Class Action Fairness Act.

5. Named Plaintiff Paul Neil Smith is a natural person domiciled in the State of Maryland.

6. Named Plaintiff Norma Sue Gibson Lanning is a natural person domiciled in the State of North Carolina.

7. Named Plaintiff Jimmy D. Blanton is a natural person domiciled in the State of South Carolina.

8. Defendant Mylan Pharmaceuticals, Inc. ("Mylan") is a for-profit corporation organized under the laws of West Virginia, and, upon information and belief, headquarters and place of decision-making in the State of Pennsylvania.

9. Defendant Teva Biopharmaceuticals USA, Inc. ("Teva"), is a corporation organized under the laws of the State of Delaware with headquarters and place of decision-making in the State of Pennsylvania; in the alternate, Teva Biopharmaceuticals USA, Inc. is a wholly-owned subsidiary of the Israeli firm Teva Pharmaceutical Industries, Ltd., and all corporate decisions are made at the parent's headquarters in the city of Petach Tikva in Israel.

10. Defendant Propst Distribution, Inc. ("Propst") is a corporation organized under the laws of the State of Alabama, and with headquarters and place of decision-making in the same state. Defendant Propst Distribution, Inc. sells pharmaceutical products under the name Qualitest Pharmaceuticals, Inc.

11. Defendant Vintage Pharmaceuticals, LLC ("Vintage") is a limited liability company organized under the laws of the State of Delaware, with, upon information and belief, partners in the State of Alabama. Defendant Vintage Pharmaceuticals, LLC either sells or sold pharmaceutical products under the name Qualitest Pharmaceuticals, Inc.

12. Class Plaintiffs are individuals resident in the United States who have been injured by propoxyphene purchased in the United States and taken prior to November 19, 2010, and are further subdivided into subclasses:

a. All plaintiffs who were injured by propoxyphene manufactured by Mylan;

b. All plaintiffs who were injured by propoxyphene manufactured by Teva;

c. All plaintiffs who were injured by propoxyphene manufactured by Propst and/or Vintage under the name Qualitest Pharmaceuticals, Inc.; and

d. All plaintiffs who were injured by propoxyphene manufactured by a combination of the foregoing Defendants.

13. All subclasses are made up of individuals across the United States, with no subclass having more than 66% of its number from any one state.

14. Each Named Plaintiff suffered medical bills and other economic loss exceeding $75,000.

15. The Class Plaintiffs consist individuals with injuries as serious or more serious than the Named Plaintiffs; in the aggregate their claimed damages will exceed $5,000,000.

16. Defendants are engaged, or have been engaged, in the manufacturing, marketing, sale, promotion and distribution of prescription pharmaceuticals, including propoxyphene, throughout the United States.

17. Defendants Mylan and Teva are corporations registered to do business in the State of Maryland.

18. All Defendants have sold pharmaceutical products within the State of Maryland, and have caused injury through their sales of propoxyphene either to Named Plaintiff Paul Neil Smith or to Maryland-domiciled members of the Class Plaintiffs.

FACTS GENERAL TO ALL PLAINTIFFS AND COUNTS

19. Propoxyphene was initially developed by Eli Lilly and Company in the 1950's and first approved by the FDA in 1957.

20. However, by 1970, the *Journal of the American Medical Association* had already published a study indicating that propoxyphene, as a painkiller, was less effective than two aspirin for most kinds of pain.

21. Propoxyphene-containing compounds, when metabolized in the human body, produce norpropoxyphene, a chemical with highly cardiotoxic qualities. Norpropoxyphene causes a number of heart dysfunctions, and can cause heart attack, stroke, and other injuries.

22. Mylan was approved to sell propoxyphene hydrochloride combined with acetaminophen in 1974.

23. Norpropoxyphene has been known to be a metabolite of propoxyphene and has been studied as a cardiotoxic compound since at least 1976.

24. In 1978, the non-governmental organization Public Citizen petitioned to ban or restrict the use of propoxyphene-containing products, claiming them an "imminent hazard" to patients' health and safety. This petition was accompanied by press releases and was generally available to any individual or organization inquiring about propoxyphene.

25. Despite prior studies, Mylan petitioned for and received permission to market a combination of propoxyphene napsalate and acetaminophen in 1986, and continued selling its other propoxyphene products.

26. Teva both purchased companies that produced propoxyphene and separately created and petitioned to sell propoxyphene products, such as its approval to sell propoxyphene napsalate and acetaminophen in 1994.

27. Vintage applied for and received permission to sell propoxyphene napsalate and acetaminophen in 1997. Since that time, Vintage and/or Propst sold propoxyphene-containing products under the name "Qualitest Pharmaceuticals, Inc."

28. By 2000, studies had emerged showing that propoxyphene-containing products were in fact less effective than safer painkillers such as ibuprofen.

29. In 2005, the government of the United Kingdom announced a withdrawal of propoxyphene from that country, stating publicly that the efficacy of propoxyphene "is poorly established and the risk of toxicity in overdose, both accidental and deliberate, is unacceptable." The U.K. government further said that "It has not been possible to identify any patient group in whom the risk-benefit [ratio] may be positive." This information was available to any manufacturer of pharmaceuticals.

30. On June 25, 2009, the European Medicines Agency banned propoxyphene from use in the European Community, citing the U.K.'s decline in deaths related to propoxyphene without a corresponding increase in deaths related to other painkillers. This information was available to any manufacturer of pharmaceuticals.

31. In July of 2009, the United States Food and Drug Administration required manufacturers of propoxyphene to conduct a study regarding the safety of their products.

32. The results of the study ordered by the FDA indicated that, even when taken at recommended doses, propoxyphene products cause significant changes to the electrical activity of the heart, which can increase the risk for serious abnormal heart rhythms that have been linked to serious adverse effects.

33. On November 19, 2010, as a result of the study, the FDA recommended against the use of propoxyphene and all manufacturers of propoxyphene ceased production.

34. At no time before the recall of propoxyphene did any Defendant conduct research on propoxyphene or evaluate propoxyphene in light of independent research.

PLAINTIFF PAUL NEIL SMITH

35. Plaintiff Paul Neil Smith was originally prescribed propoxyphene in 1988.

36. Under medical supervision and direction, Plaintiff Paul Neil Smith took propoxyphene as directed by his physicians until July of 2010.

37. The propoxyphene purchased and ingested by Plaintiff Paul Neil Smith was manufactured by Mylan.

38. In July of 2010, Plaintiff Paul Neil Smith suffered a heart attack requiring surgery.

PLAINTIFF NORMA SUE GIBSON LANNING

39. Plaintiff Norma Lanning was prescribed propoxyphene on or about the year 2009, and took it under medical supervision and direction by her physicians until approximately November of 2010.

40. The propoxyphene purchased and ingested by Plaintiff Norma Lanning was manufactured under the name Qualitest by Propst and/or Vintage.

41. In August of 2010, Plaintiff Norma Lanning was diagnosed with hearbeat issues requiring surgery.

PLAINTIFF JIMMY D. BLANTON

42. Plaintiff Jimmy D. Blanton was originally prescribed propoxyphene in 1993.

43. Under medical supervision and direction, Plaintiff Jimmy D. Blanton took propoxyphene as directed by his physicians until November of 2010.

44. The propoxyphene purchased and ingested by Plaintiff Jimmy D. Blanton was manufactured by Teva.

45. While on propoxyphene, Plaintiff Jimmy D. Blanton suffered a heart attack and developed atrial fibrillation.

COUNT I
(Negligent Failure to Test)

46. All general factual allegations are re-alleged and incorporated by reference.

47. Given the scientific and other reports available regarding propoxyphene, Defendants had a duty to engage in further tests to determine if propoxyphene was safe and effective for the uses recommended in the dosages produced.

48. At no point in time before 2009, when the FDA mandated a safety study, did Defendants conduct any research regarding the safety or efficacy of propoxyphene.

49. As a result of Defendants' failure to test, the Named Plaintiffs suffered the injuries aforementioned, underwent medical treatment, incurred medical bills, have future medical expenses due to continuing treatment for cardiac problems, and experienced pain and anguish.

50. Upon information and belief, the Class Plaintiffs suffer from similar injuries stemming from the same failure to test by Defendants.

COUNT II
(Negligent Failure to Warn)

51. All allegations stated in the previous count and all general factual allegations are re-alleged and incorporated by reference.

52. Defendants knew or should have known from independent scientific reports and other sources, including adverse event reports, that propoxyphene-containing products were likely unsafe for use as recommended.

53. It was Defendants' duty to warn the Named Plaintiffs and their physicians about all potential risks of propoxyphene and provide Plaintiffs' physicians with accurate information about the relative efficacy of the drug.

54. No Defendant adequately warned a Named Plaintiff or his or her physicians about the dangers of propoxyphene and its relative inefficacy.

55. As a result, the Named Plaintiffs were injured as aforesaid.

56. Upon information and belief, the Class Plaintiffs suffer from similar injuries stemming from the same failure to warn by Defendants.

COUNT III
(Strict Liability)

57. All allegations stated in the previous counts and all general factual allegations are re-alleged and incorporated by reference.

58. Propoxyphene is and has been an unreasonably dangerous drug for its advertised and intended purposes.

59. Defendants are engaged, or have been engaged, in the business of producing or selling propoxyphene, and are, or have been, commercial manufacturers of said drug.

60. Plaintiffs purchased, received, and injested their propoxyphene-containing products in the same condition as it was when they left Defendants' possession.

61. Defendants knew, or should have known, that patients and their attending physicians could not realize and could not detect the dangerous and harmful nature of propoxyphene. Clear warnings as to the doubtful efficacy of propoxyphene and to its cardiotoxicity should have been disseminated to overcome Defendants' advertising campaigns, labeling, and other promotional materials proclaiming the safety and efficacy of propoxyphene.

62. As a result of Defendants' marketing and promotion of said defective and unreasonably dangerous drug, the Named Plaintiffs ingested propoxyphene and have suffered injury, loss, and damages as aforesaid.

63. By reason of having marketed and promoted propoxyphene in its defective and unreasonably dangerous condition, Defendants are strictly liable to the Named Plaintiffs for their injuries, losses, and damages.

COUNT IV
(Breach of Warranty)

64. All allegations stated in the previous counts and all general factual allegations are re-alleged and incorporated by reference.

65. At all times relevant to this action, Defendants promoted and marketed propoxyphene with express and implied warranties to both patients and their treating physicians as to the drug's safety and efficacy as a painkiller.

66. Defendants knew, or should have known, that patients and their physicians were relying on these express and implied warranties.

67. At all times relevant to this action, Defendants knew or should have known that propoxyphene was a relatively ineffective painkiller and highly cardiotoxic even at the recommended dose. As such, Defendants' warranties were false, misleading, and unfounded.

68. As a result of Defendants' breach of these warranties, the Named Plaintiffs were injured as aforesaid.

69. Upon information and belief, the Class Plaintiffs suffer from similar injuries stemming from the same breaches of warranty by Defendants.

COUNT V
(Misrepresentation)

70. All allegations stated in the previous counts and all general factual allegations are re-alleged and incorporated by reference.

71. Defendants promoted propoxyphene as safe and effective for use despite its known or easily discoverable risks and known inefficacy.

72. Plaintiffs' physicians relied on Defendants' promotions in prescribing propoxyphene to Plaintiffs.

73. As a result of these misrepresentations, the Named Plaintiffs were injured as aforesaid.

74. Upon information and belief, the Class Plaintiffs suffer from similar injuries stemming from the same misrepresentations by Defendants.

COUNT VI
(Punitive Damages)

75. All allegations stated in the previous counts and all general factual allegations are re-alleged and incorporated by reference.

76. Defendants exercised substantial control over the design, testing, and labeling of their propoxyphene products. Defendants, despite being generic drug manufacturers, at any time could have required or made changes in the design or labeling, or conducted further tests.

77. There was no alteration of the propoxyphene products between the time of manufacture and the ingestion by Plaintiffs.

78. The acts of the Defendants were gross, wanton and intentional in that Defendants, at the time of Plaintiffs' purchase and ingestion of propoxyphene, had actual and constructive notice that propoxyphene was cardiotoxic even at recommended doses. Additionally, Defendants knew or should have known that propoxyphene was less effective for almost all painkilling applications than much less toxic over-the-counter pain relievers. Nonetheless, the Defendants knowingly and intentionally promoted propoxyphene as an effective painkiller and a safe drug, disregarding the published literature that warned of the risks and criticized its efficacy. The Defendants intentionally, maliciously and wantonly promoted propoxyphene as more effective than drugs research had shown to be safer and in fact more effective.

79. Defendants' gross, wanton, and intentional acts led to Plaintiff's injuries as aforesaid.

CLASS JUSTIFICATION

80. This action is appropriate for determination through Class Action Procedure for the following reasons:

a. Propoxyphene was purchased by many thousands of individuals, a significant portion of whom have suffered injury. Joining all claimants is impracticable, and, given the potential for propoxyphene-damaged hearts to cause future injury, potentially impossible. The large number of potential claimants present a level of

numerosity better handled through the class action procedure as opposed to a mass joinder of individual claims;

b. Common issues of law and fact pertaining to the determination of fault and the liability for compensatory and exemplary damages, including Defendants' likely defenses at law, predominate over the individual issue of quantum, and such issues are typical of similar claims – it would be a waste of courts' time to relitigate issues of liability on the same acts of Defendants;

c. The determination of fault and the basis for assessment of compensatory and exemplary damage may be made in the class action without the necessity of proof at that time as to the amount of those damages, thereby establishing guidelines for settlement and/or subsequent trials in individual cases if necessary;

d. Petitioners herein sustained damages of the nature described hereinabove and are suitable representatives of the class;

e. The Plaintiffs herein are represented by skilled attorneys who are experienced in handling mass torts and class actions, and who can be expected to handle this matter in an expeditious and economical matter to the best interests of the class membership;

f. The class action procedure is the superior vehicle for the efficient disposition of the issues and claims herein presented.

WHEREFORE, Plaintiff Paul Neil Smith, individually, demands judgment against Defendants in the sum of Two Million Dollars ($2,000,000.00), as compensatory damages and the sum of Two Million Dollars ($2,000,000.00) as punitive damages, plus costs.

WHEREFORE, Plaintiff Norma Sue Gibson Lanning, individually, demands judgment against Defendants in the sum of Two Million Dollars ($2,000,000.00), as compensatory damages and the sum of Two Million Dollars ($2,000,000.00) as punitive damages, plus costs.

WHEREFORE, Plaintiff Jimmy D. Blanton, individually, demands judgment against Defendants in the sum of Two Million Dollars ($2,000,000.00), as compensatory damages and the sum of Two Million Dollars ($2,000,000.00) as punitive damages, plus costs.

WHEREFORE, Class Plaintiffs pray:

1. that Defendants be required to answer this class action complaint after all legal delays have run, all in accordance with law;

2. that after due proceedings had, that this action be certified as a class action, as alleged above, for the purposes of determining the common issue of liability for appropriate damages;

3. that upon certification of the class action, the Court call for the formulation of a suitable management plan;

4. that after due proceedings had, and a trial by jury, there be judgment herein in favor of Plaintiffs and against Defendants, for all damages which are reasonable in the premises, together with legal interest thereon from the date of judicial demand until paid, and for all costs of these proceedings;

5. that the rights of the Plaintiffs and the members of the class to establish their entitlement to compensatory damages, and the amounts thereof, be reserved for determination in their individual actions when appropriate;

6. that Plaintiffs recover their costs for the prosecution of this class action;

7. that a medical monitoring class be certified, and the court award appropriate damages sufficient to establish a medical monitoring program as deemed effective by Plaintiffs' medical experts; and

8. that the Court render judgment in favor of the Plaintiffs' class awarding all damages as prayed for herein, including attorneys' fees, with all costs assessed against Defendants.

Respectfully submitted,

AARON M. LEVINE & ASSOCIATES

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Counsel for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues of material facts.

Aaron M. Levine